Stratton VA Medical Center
IRB Standard Operating Procedure: Conflict of Interest

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state, and local regulations, and ICH guidelines in the conduct of human subject research studies. Conflicts of interest have increased as the relationships of investigators with private corporations, pharmaceutical companies, and outside institutions have become more complex. Written procedures are required for conflict of interest in research.

PROCEDURE

All initial human subject research proposals submitted to the Stratton VA must contain a Stratton VA Medical Center "Conflict of Interest Disclosure Form" for each member of the research team.

If the form(s) is missing or information is incomplete, the IRB staff will contact the Principal Investigator to submit the form(s) or the missing information. Final approval for the research will not be issued until the document is completely reviewed and approved by all appropriate signatory officials.

The ACOS/R conducts a preliminary review of the disclosure statement(s). If satisfied, the ACOS/R approves the disclosure statement(s).

The ACOS/R contacts the research team member if there are questions concerning the information in the disclosure.

The Conflict of Interest (COI) Administrator, appointed by the Medical Center Director, reviews the disclosure statement from each member of the research team, and with consultation from the network Research Compliance Officer will:

determine whether there is an actual or potential conflict of interest that could impact an investigator's proposed or current research. The conflict may affect the design, conduct, or reporting of the research. The determination should evaluate:

risks to subjects

anticipated benefits, if any, to subjects

the scientific or scholarly integrity of the research

the selection of subjects

the possibility of coercion or undue influence during the consent process

the information provided to the participant

provisions for monitoring the data collected to provide for the safety of subjects

provisions to protect the privacy interests of subjects and to maintain the confidentiality of identifiable data

the credibility of the human research protection program

Determine, with the assistance of VA regional counsel, what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate the conflict.

Report findings and identify steps to manage the conflict of interest to the appropriate institutional official, the IRB, the R&D Committee, and the research team member.

Establish, with the assistance of VA regional counsel a process to allow the research team member to appeal a decision restricting the conduct of research and requiring specific steps to manage, reduce, or eliminate the conflict of interest.

Establish criteria for evaluating a research team member's appeal.

Criteria may include the nature of the research, the unique experience or qualifications required to conduct the research, the number of other investigators that may possess these qualifications, the nature and magnitude of the conflict of interest, as well as any substantial effect of the research on the conflict of interest such as increasing financial gains for the investigator.

The Conflict of Interest Administrator will maintain records of all disclosures and all actions taken by the medical center with respect to each conflicting interest for the period that the protocol records are maintained.

The IRB is responsible for identifying, reviewing, and requiring appropriate changes in protocols affected by COI for research involving human subjects.

The IRB may determine that, based on the actions and recommendations of the COI Administrator and the research team

member's COI Disclosure statement, that the research protocol should not be conducted at the institution.

The IRB should be aware of the funding arrangements and determine if the protocol addresses any COI and the management of the COI.

The IRB may determine that the Principal Investigator must disclose to the research subject financial arrangements with the research sponsor.

The disclosure to the subjects may be in discussion in the consent regarding the source of funding, the payment arrangements for the Principal investigator, the nature of the COI, how the COI is being managed, and the additional protections that have been put in place.

The additional protections may include special measures to modify the consent process, having a non-biased third party obtain the consent, and recruit subjects, or having the investigator recuse him or herself from decision making that may influence the outcome or reporting of the research results.

At the time of initial or continuing review of research, the IRB will consider the impact of the COI on the subject, the risk to the subject, the subject's willingness to participate in the research after disclosure of the conflict, and the impact on the research and the research results.

The IRB will determine if actions in addition to those required by the COI Administrator, should be taken to manage, reduce, or eliminate the COI.

The Research & Development (R&D) Committee is responsible for reviewing the actions taken by the IRB, and may approve the IRB's actions and add other stipulations or changes to the proposal, but may not disallow any of the IRB's stipulations or required changes regarding the COI.

IRB and R&D members must recuse themselves from review of protocols for which the conflict exists.

IRB members may not participate in the review of any research in which the member has a conflict of interest, except to provide information requested by the IRB. The research will not be voted upon should quorum be lost due to the absence of the member(s) with a conflict of interest.

IRB members with a conflict of interest in the research are expected to declare the reasons for the conflict to the IRB prior to the review of research.

The conflict of interest findings of the COI Administrator, IRB, and R&D are reported to the research team member and the Medical Center Director.

The Medical Center Director may add to the stipulations or requirements but may not lessen them.

In situations where the COI cannot be resolved, the Medical Center Director will make the final binding decision regarding the COI.

Any member of the research team may appeal the recommendations of the COI Administrator, IRB and/or R&D Committees in accordance with VA and medical center policies and procedures.

The research team member must comply with the final decision of the Medical Center Director in managing the COI.

The medical center may take the following actions to manage, reduce, or

eliminate COI:

Public disclosure of significant financial interests;

Monitoring of research by independent reviewers or consultants;

Modification of the research plan and/or the informed consent documents;

Disqualification from participation in all or a portion of the research;

Divestiture of significant financial interests; or

Severance of relationships that create actual or potential conflicts.

If a COI is identified after a research protocol has been approved or initiated, the COI Administrator, along with the IRB and R&D, will identify the impact of the conflict on the protocol and the research subjects, if applicable, and corrective actions to be taken to decrease the impact. Corrective actions may include:

Modifying the protocol and consent;

Reconsenting subjects or removing the research team member from a role in subject selection;

Supervision of the protocol by independent reviewers or consultant; and/or

Requiring that the COI must be disclosed in all publications or presentation resulting from the research.

When a significant COI exists and cannot be eliminated the consent form must contain a discussion of the financial arrangement, and how the conflict of interest is being managed and the additional protections that have been put in place. The inability to resolve a significant COI will be reported to the Medical Center Director through the appropriate committees.

If a research team member fails to comply with the COI policy or with corrective actions, the COI Administrator will report the failure to comply to the Medical Center Director and this failure may result in the following conditions or restrictions:

Termination of the research protocol;

Removal of the investigator from the research team; or

Revocation of the privilege to conduct research within the VA.

The research team member may also be sanctioned by the Public Health Service, Food and Drug Administration, or other applicable entities depending on the seriousness of the non-compliance and the determination of the research sponsor.